terminate, suspend, restrict, or require modification of any activity if it is determined that such measures are required to conserve wildlife, fish, or their habitat. Prior to taking action to terminate, suspend, restrict, or require modification of an activity under this section, the responsible Forest Officer shall give affected parties reasonable prior notice and an opportunity to comment, unless it is determined that doing so would likely result in irreparable harm to conservation of fish, wildlife, and their habitat.

(f) Nothing in this section affects subsistence activities in accordance with § 241.23 of this subpart or other applicable law.

§ 241.23 Taking of fish and wildlife.

(a) The taking of fish and wildlife by hunting, trapping, and fishing from lands subject to the rules of this Subpart is authorized in accordance with applicable State and Federal law.

(b) To the extent consistent with the conservation of fish and wildlife and their habitat in accordance with recognized scientific management principles, local rural residents who depend upon the Chugach National Forest for subsistence needs shall continue to have the opportunity to engage in a subsistence way of life on the lands to which this Subpart is applicable pursuant to applicable State and Federal law.

(c) To the extent consistent with the conservation of fish and wildlife and their habitat, the continuance of existing uses and the future establishment and use of temporary campsites, tent platforms, shelters, and other temporary facilities and equipment directly and necessarily related to the taking of fish and wildlife may be authorized in accordance with applicable law and regulations. However, the Forest Supervisor may restrict or prohibit facilities or uses on the Copper River-Rude River addition or Copper River-Bering River area if it is determined, after adequate notice to the affected parties, that the continuance of such facilities or uses would materially interfere with or adversely affect the conservation of fish and wildlife and their habitat.

Date: March 7, 1989.

F. Dale Robertson,

Chief.

[FR Doc. 89-7617 Filed 3-30-89; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 795 and 799

[OPTS-42065B; FRL-3546-6]

Diethylene Glycol Butyl Ether and Diethylene Glycol Butyl Ether Acetate; Pharmacokinetics Test Standard and Reporting Requirements

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to amend the pharmacokinetics test standard in 40 CFR 795.225 by revising the dose occlusion requirements for diethylene glycol butyl ether (DGBE) and diethylene glycol butyl ether acetate (DGBA) in the conduct of the study, reducing the dermal exposure time of the test animals to DGBA and DGBE from 96 to 24 hours, and adding a requirement to administer a neat low dose of DGBE to an additional group of animals. EPA is also proposing to amend the associated test rule in 40 CFR 799.1560 by modifying the submission of the progress and final pharmacokinetics test reports to EPA. These amendments are in response to the test sponsor's request to amend the rules because of documented difficulties encountered in attempting to perform the pharmacokinetics test.

DATES: Submit written comments on or before May 1, 1989. If persons request an opportunity to submit oral comments by May 1, 1989, EPA will hold a public meeting on this proposed rule in Washington, DC. For further information on arranging to speak at the meeting, see Unit VI of this preamble.

ADDRESS: Submit written comments, identified by the document control number (OPTS-42065B) in triplicate to: TSCA Public Docket Office (TS-793), Office of Toxic Substances, Environmental Protection Agency, Rm. NE-G004, 401 M Street SW., Washington, DC 20460. (202) 554-1404.

FOR FURTHER INFORMATION CONTACT: Michael M. Stahl, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Rm. EB-44, 401 M Street SW., Washington, DC 20460, (202) 554-1404, TDD (202) 554-0551.

SUPPLEMENTARY INFORMATION: EPA is proposing to amend the dermal pharmacokinetics test standard and final rule for DGBE and DGBA by reducing the exposure time to the test substance in the pharmacokinetics test and extending the reporting deadlines.

I. Background

EPA issued a final rule under TSCA section 4(a)(1)(A) and (B), published in the Federal Register of February 26, 1988 (53 FR 5932), that established health effects testing requirements for DGBE and DGBA. The rule required dermal pharmacokinetics testing in rats to determine the absorption and biotransformation of DGBE administered dermally, and the dermal absorption of DGBA. The test standard, in 40 CFR 795.225(b)(2)(iv)(E), required that rats be dosed once dermally, and that the dose be kept on the skin for the duration of the study (96 hours). After dosing, the animals were to be placed in metabolism cages for excreta collection for at least 96 hours and, if necessary, daily thereafter until at least 90 percent of the dose had been excreted, or until 7 days after dosing. The final rule required completion of this test and submission of a final report by April 11, 1989, 12 months after the effective date of the final rule, 40 CFR 799.1560(c)(4)(ii).

On July 25, 1988, the Chemical Manufacturers Association (CMA) contacted EPA concerning the pharmacokinetics test requirement to occlude the dosed area with an aluminum patch secured in place with adhesive tape, 40 CFR 795.225(b)(2)(ii)(B). CMA requested that the test sponsor, Eastman Kodak, be allowed to use a glass containment device to occlude the dosed area instead of the aluminum foil patch required by the test standard (Ref. 1). EPA requested that CMA submit a formal request to make this change. CMA did so on September 8, 1988 (Ref. 2).

In the interim, CMA reported difficulties with test substance leakage and with keeping the glass cell containment device on the animals' backs for more than 24 hours (Ref. 3). EPA officials had several discussions and a meeting with CMA and Eastman Kodak concerning alternative techniques which might enable a 96-hour dermal exposure (Refs. 5 and 6). EPA also gave CMA a copy of a similar study which had achieved a 96-hour dermal exposure time (Refs. 8 and 9). As a result, the Eastman Kodak laboratory conducted a number of pilot studies to test different wrapping techniques, occlusive devises, and brands of glue (Refs. 2, 6, 10). None of these studies was successful in maintaining the test substance in contact with the animals' backs for more than 24 to 48 hours (Ref. 2).

CMA, therefore, proposed that the requirement to keep the test substance on the animals' backs be reduced from

96 hours to 24 hours. CMA also requested that the requirement to occlude the dosed area with an aluminum patch be eliminated because it had been shown to be ineffective (Ref. 2). CMA proposed that any test material remaining on the skin 24 hours after application be washed off at that time and the cell removed. Radiolabelled material in the wash would be accounted for in the total recovery, and excreta would continue to be collected and analyzed at 48, 72, and 96 hours, and daily thereafter up to 7 days if necessary. CMA also proposed repeating the already completed low dose DGBA study using this procedure so that the test methodologies would be comparable, even though it appeared that all the low dose DGBA had been absorbed by 24 hours (Ref. 2).

Precedent exists for this proposed modification, since other section 4 rules and consent orders have required dermal exposure times of 24 hours or less. The only other final test rule, besides DGBE and DGBA, which required a dermal pharmacokinetics test with a 96-hour exposure period was 2-ethylhexanoic acid (EHA), 40 CFR 799.1650 (Ref. 7). Eastman Kodak was also the test sponsor for this experiment with EHA. No leakage problems were encountered with EHA, however, because EHA was absorbed before the glass cells dislodged from the animals' backs (Ref. 4).

In the course of the discussions between EPA and CMA, EPA suggested and CMA agreed that a neat (i.e. undiluted, nonaqueous) low dose would make the data more comparable to the neat high dose in the pharmacokinetics study, and would avoid introducing confusion due to the different absorption properties of water (Ref. 6). At the same time, there are advantages to having an aqueous low dose of DGBE. The low dose allows comparison with the aqueous low dose of DGBE in the subchronic toxicity and neurotoxicity studies (Ref. 2). It also mimics a common condition of human exposure, in which a DGBE-containing product is diluted in water. Kodak has, therefore, volunteered to add another group of eight animals so that the low-dose DGBE experiment could be done with both aqueous and neat doses (REf. 2). Accordingly, EPA proposes this modification and believes it will produce more useful results.

CMA did not offer to conduct a neat low-dose test with DGBA, although, as with DGBE, it would improve comparability of low-dose and high dose data.

There is less reason to use an aqueous low dose of DGBA, since it is not diluted in water in consumer applications. Further, there are no required studies of DGBA with a aqueous dilutions that EPA could compare with the absorption studies. Although not specifically required by the test standard, it is EPA's understanding that Eastman Kodak will use an aqueous low dose DGBA.

Eastman Kodak has suspended the pharmacokinetics testing of DGBE and DBGA until the problems discussed above can be resolved. CMA has requested an extension of the reporting deadline for the pharmacokinetics study that would require submission of final reports 10 months after CMA is notified about EPA's decision concerning the proposed modifications. Kodak supported CMA's request with a detailed plan listing the time to complete key study phases (Ref. 10). EPA agrees that the reporting deadlines should be extended. However, due to the considerable experience that Eastman Kodak has had to date in attempting to perform this test, and the fact that certain study phases can be run concurrently, EPA believes that 8 months is sufficient to complete the test and submit results.

II. Proposed Modifications

Based on the difficulties encountered and documented by Eastman Kodak in attempting to perform the pharmacokinetics test of DGBE and DGBA as required by the section 4 test rule, EPA proposes to modify the pharmacokinetics test standard as follows:

Section 795.225(b)(2)(iv)(E) will require that the test substance be kept on the animal for 24 hours instead of 90 hours. After 24 hours, any test material remaining on the skin will be washed off and the containment cell removed. Radiolabeled material in the wash will be accounted for in the total recovery. Urine and feces will be collected at 8, 24, 48, 72, and 96 hours after dosing, and if necessary, daily thereafter until at least 90 percent of the dose has been excreted or until 7 days after dosing (whichever occurs first).

Under § 795.225(b)(2)(ii)(B), EPA proposes to eliminate the requirement to occlude the dosed area with an aluminum foil patch secured in place with adhesive tape.

In order to produce better data, CMA has volunteered to test two low doses of DGBE, one neat and one a 10 percent aqueous solution. EPA, therefore, proposes that § 795.225(b)(2)(ii)(A) be modified to reflect this.

III. Proposed Extension

Due to the need to suspend pharmacokinetics testing because of technical problems, it is proposed that the reporting deadlines under § 799.1560(c)(4)(ii) (A) and (B) be modified to allow 8 months from the effective date of the amendment for the completion of the test and submission of final results. One progress report would be due 6 months after the effective date of the final amendment.

IV. Economic Analysis

The modifications in this proposed amendment will not significantly alter the cost of testing. Thus, the economic analysis for the final test rule for DGBE and DGBA is unchanged.

V. Issue for Comment

Should the low dose of DGBA be administered neat for better comparison with the neat high dose, or would an aqueous dilution of the low dose which is equal in volume to the high dose be a better study of absorption properties?

VI. Public Meetings

If persons indicate to EPA that they wish to present oral comments on this proposed amendment to EPA officials who are directly responsible for developing the amendment and supporting analyses, EPA will hold a public meeting after the close of the public comment period in Washington, DC. Persons who wish to attend or to present comments at the meeting should call the TSCA Assistance Office (TAO): (202) 554-1404, by May 1, 1989. A meeting will not be held if members of the public do not indicate that they wish to make oral presentations. While the meeting will be open to the public, active participation will be limited to those persons who arrange to present comments and to designated EPA participants. Persons wishing to attend should call the TAO before making travel plans to verify whether a meeting will be held.

Should a meeting be held, EPA would transcribe the meeting and include the written transcript in the rule-making record. Participants are invited, but not required, to submit copies of their statements prior to or on the day of the meeting. All such written materials will become part of EPA's record for this rulemaking.

VII. Rulemaking Record

EPA has established a record for this rulemaking (docket number OPTS-42085B). This record includes information considered by the EPA in developing this proposed amendment and appropriate Federal Register notices.

This record includes the following information:

A. Supporting Documentation

(1) Federal Register notices consisting of:

(a) Notice of proposed test rule for DGBE and DGBA (51 FR 27880; August 4, 1986).

(b) Notice of final test rule for DGBE and DGBA (53 FR 5932; February 26, 1988).

(2) Communications consisting of:

(a) Letters.

(b) Contact reports of telephone conversations and meetings.

B. References

(1) USEPA. Contact report of phone conversation between Fred DiCarlo, Health and Environmental Review Division, Office of Toxic Substance (OTS), and Dr. Carol Stack, Chemical Manufacturers Assoc. (CMA), Washington, DC (July 25, 1988).

(2) CMA. Letter from Dr. Geraldine Cox, CMA, to the Director; Office of Compliance Monitoring, Office of Pesticides and Toxic Substances, USEPA, (September 8, 1988).

(3) USEPA. Contact report of phone conversation between Catherine Roman, Test Rules Development Branch (TRDB), and Dr. Carol Stack, CMA. (August 3, 1988).

(4) USEPA. Contact report of phone conversation between Catherine Roman, TRDB, and Dr. Carol Stack (CMA). (August 29, 1988).

(5) USEPA. Contact report of phone conversation between Catherine Roman, TRDB, and Dr. Carol Stack, CMA. (August 5, 1988).

(6) USEPA. Contact report of meeting between EPA officials and Dr. Carol Stack, CMA, and Dr. Derek Guest, Eastman Kodak. (August 23, 1988).

(7) Notice of final test rule for 2-Ethylhexanoic Acid (51 FR 40318; November 6, 1986).

(8) Southern Research Institute, Birmingham, Alabama 35255–5305. "Absorption and Disposition of 2-mercaptobenzothiazole-Ring-UL-^{14}C and 2-Mercaptobenzothiazole Disulfide-Ring-UL-^{14}C in Fischer 344 Male and Female Rats and Female Guinea Pigs Dosed Topically." SoRI-86–1200, Report 5873–V, Contract RA–4.0–SRI PHARM. Contracted by CMA, Washington, DC. (May 27, 1987).

(9) USEPA. Letter from Richard Troast, TRDB, to Dr. Carol Stack, CMA. (October 19, 1988).

(10) CMA. Letter and attachments from Dr. Carol Stack, CMA, to the Director, Office of Compliance Monitoring, Office of Pesticides and Toxic Substances, USEPA (November 16, 1988).

VIII. Other Regulatory Requirements

A. Executive Order 12291

EPA judged that the final test rule was not subject to the requirement of a Regulatory Impact Analysis under Executive Order 12291. EPA has determined that the proposed modifications to the rule do not alter this determination.

This proposed amendment was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291. Any written comments from OMB to EPA, and any EPA response to those comments, are included in the rulemaking record.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act, (5 U.S.C. 601 *et seq.*, Publ. L. 96–354, September 19, 1980), EPA certified that the final test rule would not have a significant impact on a substantial number of small businesses. The proposed changes to the final rule will not change this determination.

C. Paperwork Reduction Act

The information collection requirements associated with this rule have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* and have been assigned OMB control number 2070–0033.

EPA has determined that this proposed rule does not change existing recordkeeping or reporting requirements nor does it impose any additional recordkeeping or reporting requirements on the public.

Send comments regarding this rule to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

List of Subjects in 40 CFR Parts 795 and 799

Chemicals, Environmental protection, Hazardous substances, Laboratories, Recordkeeping and reporting requirements, Testing.

Dated: March 21, 1989.

Victor J. Kimm,

Acting Assistant Administrator for Pesticides and Toxic Substances.

Therefore, it is proposed that 40 CFR Chapter I, Subchapter R, be amended as follows:

PART 795—[AMENDED]

1. In Part 795:

a. The authority citation would continue to read as follows:

Authority: 15 U.S.C. 2603.

b. In § 795.225 by revising paragraphs (b)(2)(ii) (A), (B), and (iv)(E) to read as follows:

§ 795.225 Dermal pharmacokinetics of DGBE and DGBA.

* * * * *

(b) * * *

(2) * * *

(ii) *Dosage and treatment.* (A) Two doses of DGBA shall be used in the study, a "low" dose and a "high" does. Three doses of DGBE shall be used in the study, a neat "low" dose, an aqueous "low" dose, and a neat "high" dose. When administered dermally, the "high" dose level should ideally induce some overt toxicity such as weight loss. The "low" dose level should correspond to a no observed effect level.

(B) For dermal treatment, the doses shall be applied in a volume adequate to deliver the prescribed doses. The backs of the rats should be lightly shaved with an electric clipper shortly before treatment. The dose shall be applied with a micropipette on a specific area (for example, 2 cm^2) on the freshly shaven skin.

* * * * *

(iv) * * *

(E) The high and low doses of ^{14}C–DGBE and ^{14}C–DGBA shall be kept on the skin for 24 hours. After application, the animals shall be placed in metabolism cages for excreta collection. After 24 hours, any test material remaining on the skin will be washed off and the containment cell removed. Radiolabeled material in the wash will be accounted for in the total recovery. Urine and feces shall be collected at 8, 24, 48, 72, and 96 hours after dosing, and if necessary, daily thereafter until at least 90 percent of the dose has been excreted or until 7 days after dosing (whichever occurs first).

* * * * *

PART 799—[AMENDED]

2. In Part 799:

a. The authority citation would continue to read as follows:

Authority: 15 U.S.C. 2603, 2611, 2625.

b. In § 799.1560 by revising paragraphs (c)(4)(ii) (A), (B), and (e) to read as follows:

§ 799.1560 Diethylene glycol butyl ether and diethylene glycol butyl ether acetate.

* * * * *

(c) * * *

(4) * * *

(ii) * * *

(A) The pharmacokinetics tests shall be completed and the final reports submitted to EPA within 8 months of the effective date of the final amendment.

(B) A progress report shall be submitted to EPA 6 months from the effective date of the final amendment.

* * * * *

(e)(1) 40 CFR 799.1560 is effective on April 11, 1988 except for the provisions of paragraphs (c)(4)(ii) (A) and (B) which are effective on (insert 44 days after publication of the final rule).

(2) The guidelines and other test methods cited in this section are referenced here as they exist on April 11, 1988 except for the provisions in 40 CFR 795.225(b)(2)(ii) (A) and (B) and (iv)(E) of this Chapter, which are effective on (insert 44 days after publication of the final rule).

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[FR Doc. 89-7827 Filed 3-30-89; 8:45 am]
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